Module 7: Basic Compliance/Noncompliance of Plans

Goal To provide instructions to in-plant inspection personnel for determining the compliance/noncompliance of an establishment's plans.

Objectives After completing this module, participants will be able to:

1. Know the regulatory requirements for HACCP plans/procedures.
2. Be able to verify that HACCP plans/procedures meet regulatory requirements using checklists.
3. Be able to document findings and take enforcement actions when regulatory requirements are not met.
4. List the preparatory steps for a plant level awareness meeting.
5. Answer whether an inspector may take the plant's HACCP plan to the government office to review prior to an awareness meeting.
6. State the purpose, time allocation, and scheduling of the HACCP awareness process.

Plant Awareness Meetings

When the monumental changes that accompany HACCP implementation come to rest at your door, you will spend a lot of time talking to plant management. One of the very first things that will be necessary is to understand the plant's HACCP plan prior to performing basic compliance/noncompliance procedures. In order to accomplish this, the IIC should hold an awareness meeting between inspection personnel and plant personnel.

Helpful communication techniques and tips that can make the meeting proceed more smoothly will be presented in a future module.

First, the IIC will decide who will be involved in the meeting. Key management personnel and inspection personnel performing HACCP inspection procedures should participate in this meeting.

Second, the IIC will determine how much time will be needed for the meeting. The amount of time will vary according to the plant size and complexity of the plans. One to four days may be needed for these meeting in large plants. From four hours to one day may be all that is needed in small and very small plants.

In slaughter plants, the IIC will handle this as an assignment of work activity. The time allocated to inspectors may vary according to their area of responsibility. In processing plants without an on-site supervisor, the IIC will talk to the circuit supervisor to determine the amount of time to be spent on this activity.

The IIC might request an opportunity to review the HACCP plan prior to the awareness meeting to help decide how much time will be needed for the meeting. An outline can be made for the items to be discussed. Like the SSOP, however, the HACCP plan is property of the establishment.

When inspectors are involved in the awareness process and are responsible for carrying out the SSOP procedures, SSOP procedures will be accomplished first and then move to the awareness activity. This includes following through to completion on the taking of official control actions when they encounter adulterated or mislabeled products. Also, the accomplishment of the awareness process will not impact upon the giving of breaks to on-line inspection personnel.

Since HACCP plans are plant-specific, inspection personnel can not effectively perform HACCP procedures until they understand the plan. This meeting provides an opportunity for inspection personnel to familiarize themselves with the plan. They can also learn some things about the plan in operations, such as, where the HACCP records are kept, how to gain access to the computer, where the CCPs are located, etc.

HACCP Plan

The establishment has the responsibility for developing, implementing, validating, verifying, and reassessing the HACCP plan. Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more hazards that are reasonably likely to occur, based on the hazard analysis conducted. A single HACCP plan may encompass multiple products within a single processing category, e.g., bologna and cooked salami, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.

The HACCP regulation places all products into nine processing categories. This means that several products can be produced under one HACCP plan provided any of the features or requirements of the plan that are unique to a specific product are clearly listed in the plan and observed in the operation. For example, an establishment might have a HACCP plan for the fully cooked—not shelf stable processing category that includes cooked beef, fully cooked pork ham, fully cooked turkey ham, frankfurters, bologna, cooked salami, and any other products that are fully cooked and not shelf stable. Other establishments might have a HACCP plan for the same fully cooked—not shelf stable processing category that covers only one product, such as beef bologna. Every establishment is different and, therefore, the process is unique to the establishment. That is why HACCP plans must be plant-specific, even though the process category covered in the plans from establishment to establishment might be the same.

The HACCP plan implemented must be validated. This means the establishment has conducted validation activities to determine that the HACCP plan is functioning as intended. The establishment's records include multiple results that verify the monitoring of CCPs and conformance with critical limits, and after each deviation from a critical limit (if any), subsequent results that support the adequacy of corrective action(s) in achieving control at the CCP. When inspection personnel are performing the basic compliance procedure, using the checklist, they will need to look at the establishment's records to ensure that this requirement has been met. The purpose of this procedure is to determine that validation activities have been conducted; not to determine if the plan is scientifically sound.

Regulations 417.7(b) state that the HACCP plan must be developed by an individual who has completed a course of instruction in the application of the seven principles to meat or poultry product processing. This course must include a segment on the development of a HACCP plan for a specific product and on record review. It is not necessary for the establishment to provide physical evidence this training was attended, such as a certificate of completion.

Regulatory Requirements:

1. *Every establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.* §417.2(a)(1)

2. *A flow chart describing the steps of each process and product flow in the establishment shall be prepared.* §417.2(a)(2)

3. *The intended use or consumers of the finished product shall be identified.* §417.2(a)(2)

4. *The HACCP plan must list the food safety hazards that must be controlled.* §417.2(a)(1) A listed hazard must be of such a nature that its prevention, elimination, or reduction to acceptable levels is essential to the production of a safe food. An example of eliminating bacteria or reducing numbers to an acceptable level is the cooking step in a cooked sausage process.

5. *The HACCP plan must list the critical control points for each of the identified food safety hazards that could be introduced inside and outside the establishment.* §417.2(c)(2) Identification of CCPs for controlling microbial hazards throughout the production process is particularly important because these hazards are the primary cause of food-borne illness.

6. *The plan must list the critical limits that must be met at each of the critical control points.* §417.2(c)(3) A critical limit is the value to which a process must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the identified physical, biological, or chemical food safety hazard.

7. *The plan must contain the procedures and frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits.* §417.2(c)(4) Monitoring is an integral part of HACCP and consists of observations or measurements taken to assess whether a CCP is within the established critical limit.

8. *The plan shall identify the corrective actions to be followed in response to a deviation from a critical limit.* §417.2(c)(5)

9. *The plan provides for a record keeping system that documents the monitoring of critical control points.* §417.2(c)(6)

10. *The plan must list the verification procedures and the frequency with which those procedures will be performed.* §417.2(c)(7)

11. *The plan shall be signed and dated by the responsible establishment official.* §417.2(d)(2) The HACCP plan shall be dated and signed when it is initiated, when it is modified, and at least annually.

Procedure 03A01 - Basic Compliance/Noncompliance

The compliance standard for the basic compliance procedure in the Inspection System Procedure Guide (ISP) is as follows:

The establishment has conducted a hazard analysis. The hazard analysis includes food safety hazards reasonably likely to occur, a flow chart, and identifies intended use or consumers of the finished product(s) [FSIS Directive 5000.1, IIB1a(1)(2)(3)].

If one or more food safety hazards are reasonably likely to occur, establishment has a written HACCP plan for each product (process) [FSIS Directive 5000.1, IIB1b(1)].

The establishment has conducted validation activities, and records include multiple results that verify monitoring of CCPs and conformance with critical limits, and after each deviation from a critical limit (if any), subsequent results support adequacy of corrective action(s) in achieving control [FSIS Directive 5000.1, IIB1b(2)].

The establishment reassesses the hazard analysis—if, after hazard analysis revealed no food safety hazards reasonably likely to occur, there was a change that could reasonably affect whether a food safety hazard exists [FSIS Directive 5000.1, IIB1c(1)].

Before producing a new product for distribution, the establishment has conducted a hazard analysis and has an applicable HACCP plan. If in distribution for more than 90 days, HACCP plan has been validated [FSIS Directive 5000.1, IIB1c(2)].

If the HACCP plan covers more than one product, all products are within one of the specified HACCP processing categories [FSIS Directive 5000.1, IIB2a].

The HACCP plan(s): lists food safety hazard(s) identified in hazard analysis (exception: thermally processed/commercially sterile products produced in accordance with part 318, subpart G, or part 381, subpart X); lists CCPs for each food safety hazard; lists critical limits to be met at each CCP; lists procedures to be used to monitor each CCP and frequency with which performed; identifies corrective actions to be followed in response to a deviation from a critical limit at a critical control point; lists verification procedures and frequency with which performed [FSIS Directive 5000.1, IIB2b-f].

The recordkeeping system documents monitoring of CCPs and includes records with actual values and observations [FSIS Directive 5000.1, IIB3].

The responsible establishment official signed and dated the HACCP plan upon initial acceptance, and at least annually thereafter. If HACCP plan is modified, responsible establishment official signed and dated [FSIS Directive 5000.1, IIB4ab].

The basic HACCP compliance/noncompliance procedure from the ISP is:

When regulations first apply and as appropriate thereafter, review hazard analysis, HACCP plan(s), and recordkeeping.
Make determination about compliance with regulatory requirements.

Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

The HACCP/Pathogen Reduction Regulation is to be implemented on January 26, 1998 for large plants, January 25, 1999 for smaller establishments, and January 25, 2000 for very small establishments. Inspection personnel perform the basic compliance/noncompliance procedure at the time of start-up, or initial implementation and any time the HACCP plan is modified. This procedure must also be performed annually shortly after the implementation anniversary date. This procedure should be performed shortly after the anniversary date even if the plan has been revised during the year and the procedure was performed at that time. This is an each occurrence procedure and is always performed and documented as an unscheduled procedure.

It is also possible (though unlikely) that a hazard analysis will reveal no food safety hazards that are likely to occur. For example if an establishment is only reboxing packaged product, no safety hazard may exists. If no safety hazard exists in this process used for the product, a HACCP plan would not be required unless a change took place that could include a food safety hazard. For example, if the same plant started slicing and packaging the product they had only been reboxing, a HACCP plan would probably be required. The change in the process would require the establishment to conduct a hazard analysis and if a hazard is found that is reasonably likely to occur, a HACCP plan must be developed before they start the slicing operation. When the plan is implemented, inspection personnel perform 03A01 basic compliance procedure to ensure that the plan meets regulatory requirements.

FSIS does not approve HACCP plans, but will use the HACCP Systems Basic Compliance Checklist (FSIS Form 5000-1) to assure that every HACCP plan has met the basic regulatory requirements. Some plants will have several HACCP plans. If this is the case, inspection personnel will be required to perform basic compliance procedure 03A01 and complete the checklist for each one of the plans to ensure that each plan has met the regulatory requirements. If the establishment has **not** met regulatory requirements for one HACCP plan, but has for others, withholding action would be taken **only** against the production under the one HACCP plan. For example, an establishment has a HACCP plan for the fresh ground process because they are producing fresh pork sausage and also has a HACCP plan for the fully cooked—not shelf stable process because they are producing cooked sausage products. If when the basic compliance procedure is performed, the HACCP plan for the fully cooked—not shelf stable process meets the regulatory requirements but the plan for the fresh ground process did not, withholding action would be taken only against the production under the fresh ground process.

The checklist is written in a manner to avoid giving approval or the perception of approval by FSIS. We as regulators are there to find noncompliance, not to confer compliance on all activities that an establishment may be conducting. Establishments are responsible for meeting **all regulatory requirements**, whether FSIS checks them or not.

The checklist consists of statements about what an establishment is not doing and provides check boxes labeled "YES." If any of the statements on the checklist is answered **"YES"**, a basic regulatory requirement has not been met. Any time noncompliance is found while performing the basic compliance procedure, it should be completely described on a Noncompliance Record (NR).

When performing the basic compliance/noncompliance procedure, inspection personnel are to use the checklist to ensure compliance with the basic regulatory requirements. The basic regulatory requirements have been included on the checklist.

Finding noncompliance with the basic HACCP requirements of the regulations supports the withholding of inspection to prevent the production of products until the plant returns to compliance. An IIC, who determines that an establishment has failed to meet one or more of these requirements, is to take the following steps:

1. Advise establishment management orally of the findings on which the intended action is based and (as soon as possible and by the end of his or her tour of duty) confirm with a copy of the NR that documents the noncompliance finding(s).

2. Refuse to permit the labeling, stamping, or tagging of any livestock product or poultry product produced under the noncomplying conditions as "inspected and passed" or "inspected for wholesomeness".

3. Identify all possibly adulterated livestock and/or poultry products as "U.S. Retained".

4. Notify the DO of the action(s) taken, and if the establishment does not initiate action immediately to bring itself into compliance—

   notify the DO (which will assign a CO), and

   in conjunction with the CO, develop a case file and take further action as appropriate.

If noncompliance with the requirements involves **only** a failure that the responsible establishment official can correct effectively and immediately, (for example, the HACCP plan is not signed and/or dated), before taking **any** enforcement actions, inspection personnel will provide establishment management an opportunity to bring the

establishment into compliance. If the HACCP plan is not signed and/or dated and the establishment immediately corrects this noncompliance, inspection personnel will document the noncompliance on an NR with a statement that the situation was corrected immediately.

If noncompliance with any of the requirements involves a failure that **cannot** be corrected effectively and immediately, inspection personnel will take the following enforcement actions.

If there is **no** evidence that a hazard analysis has been performed, in-plan inspection personnel document the noncompliance on an NR and initiate withholding actions.

If the HACCP plan does **not** list the food safety hazards that must be controlled, inspection personnel document the noncompliance on an NR and initiate withholding actions.

If a flow chart is **not** present, in-plant inspection personnel document the noncompliance on an NR and initiate withholding actions.

If the intended use or consumers of the product is **not** identified, in-plant inspection personnel document the noncompliance on an NR and initiate withholding actions.

If the establishment's hazard analysis reveals one or more hazards that are reasonably likely to occur and a HACCP plan is **not** available for one or more products, in-plant inspection personnel document the noncompliance on an NR and initiate withholding actions.

If the establishment records do **not** indicate validation activities have been conducted, in-plant inspection personnel will document the noncompliance on an NR and initiate withholding actions.

If the establishment is producing a new product for distribution without conducting a hazard analysis and does **not** have an applicable HACCP plan, in-plant inspection personnel will document the noncompliance on an NR and initiate withholding actions.

> For example, if an establishment operating under the HACCP regulations develops a new product that is not covered by an existing plan, the establishment must conduct a hazard analysis. If a safety hazard is found reasonable likely to occur, the establishment must develop a HACCP plan before the product is distributed.

If the establishment has been distributing a new product for more than 90 days **without** a **validated** HACCP plan that covers the product, in-plant inspection personnel will document the noncompliance on an NR and initiate withholding actions.

> For example, if the establishment in the above example has developed a HACCP plan for a new product, they may distribute the product for ninety (90) days while they validate this plan.

If a HACCP plan covers more than one product and the products are not all within one of the nine processing categories specified in §417.2(b)(1)(2), in-plant inspection personnel document the noncompliance on an NR and initiate withholding actions.

If the HACCP plant does **not** list the critical control points for each of the identified food safety hazards that could be introduced inside and outside the establishment, in-plant inspection personnel document the noncompliance on an NR and initiate withholding actions.

If the critical limits that must be met at the critical control points are **not** listed in the HACCP plan, in-plant inspection personnel document the noncompliance on an NR and initiate withholding actions.

If the monitoring procedures and the frequencies at which those procedures will be performed are **not** in the HACCP plan, in-plant inspection personnel will document the noncompliance on an NR and initiate withholding actions.

If the HACCP plan does **not** identify the corrective actions to be followed in response to a deviation from a critical limit, in-plant inspection personnel will document the noncompliance on an NR and initiate withholding actions.

If the plan does **not** contain the verification procedures and the frequency with which those procedures will be performed, in-plant inspection personnel will document the noncompliance on an NR and initiate withholding actions.

If the HACCP plan does **not** have a recordkeeping system that documents the monitoring of critical control points, in-plant inspection personnel document the noncompliance on an NR and initiate withholding actions.

If there is **no evidence** that the plan has been implemented, in-plant inspection personnel will document the noncompliance on an NR and initiate withholding actions.

Remember, when documenting noncompliance with the **basic** HACCP regulatory requirements, a trend indicator **will not be marked on the NR or PS** because the code is specific to the basic compliance/noncompliance procedure.

If the establishment does not initiate action immediately to bring itself into compliance, the IIC should notify the District Office about the actions taken. The District Office will direct the next enforcement action. The District Manager will assign a Compliance Officer who will work with the IIC to develop a case file. The District Manager will give you further instructions to take, as appropriate. Based on the specific findings, the District Manager may place the withholding action in abeyance. When this is done, the plant is required to provide written assurances that it will bring itself into compliance. **This does not mean the enforcement action has ended. If the plant fails to follow its written assurances and bring itself into compliance, the withholding will be reinitiated.**

SSOP Documentation and Enforcement Actions

As of January 27, 1997, all establishments were required to have Standard Sanitation Operating Procedures (SSOPs) that met five regulatory requirements. The ISG task 02D01a2 will be replaced with ISP procedure 01A01 on January 26, 1998, for establishments that come under the HACCP regulations. ISP procedure 01A01 does **not** need to be performed just because HACCP is being implemented. **All SSOPs still must meet the five regulatory requirements describing the procedures the establishment will conduct daily to prevent direct contamination or adulteration of product.**

In accordance with FSIS Directive 5000.1, a checklist (FSIS Form 5000-2) will be used to record findings of noncompliance with the requirements of regulations 416.11. In-plant inspection personnel will use the same procedures for documenting SSOP noncompliance findings and initiating enforcement actions as they use for HACCP noncompliance findings. For example, if the SSOP has been modified and the modification has not been signed and dated, inspection personnel would return the modification to the establishment for signing and dating. The finding is documented on an NR along with the statement that the finding was immediately corrected. This is the same documentation that applies to a HACCP plan or modification that is not signed and dated.

If inspection personnel find that the establishment's SSOPs **do not** meet regulatory requirements and **can not** be corrected immediately, the following enforcement actions must be initiated:

1. Advise establishment management orally of the findings on which the intended action is based and (as soon as possible and by the end of his or her tour of duty) confirm with a copy of the NR that documents the noncompliance finding(s).

2. a. Refuse to permit the labeling, stamping, or tagging of any livestock product or poultry product produced under the noncomplying conditions as "inspected and passed" or "inspected for wholesomeness".

   b. Identify all possibly adulterated livestock and/or poultry products as "U.S. Retained".

   c. Identify all violative equipment, utensil(s), room(s), or compartment(s) as "U.S. Rejected".

3. Notify the DO of the action(s) taken, and if the establishment does not initiate action immediately to bring itself into compliance—

notify the DO (which will assign a CO), and in conjunction with the CO, develop a case file and take further action as appropriate.

If the establishment does **not** have written SSOPs that describe the procedures the establishment conducts daily to prevent direct contamination or adulteration of product, inspection personnel will document the noncompliance on an NR and initiate withholding actions.

If the SSOPs do **not** identify which of the procedures are pre-operational, inspection personnel will document the noncompliance on an NR and initiate withholding actions.

If the SSOPs do **not** specify the frequency with which the establishment will conduct each procedure, inspection personnel will document the noncompliance on an NR and initiate withholding actions.

If the SSOPs do **not** identify the establishment employee or employees responsible for implementing and maintaining specified procedures, inspection personnel will document the noncompliance on an NR and initiate withholding actions.

If the establishment does **not** have identified records, that on a daily basis, document implementation and monitoring of the SSOPs and any corrective actions taken, inspection personnel will document the noncompliance on an NR and initiate withholding actions.

Remember, when documenting noncompliance with the **basic** SSOP regulatory requirements, a trend indicator **will not be marked on the NR or PS** because the code is specific to the basic compliance/noncompliance procedure.

As a review of the material covered in this module, the facilitator will cover the following points with you.

1. What is the purpose of the plant awareness meeting?

2. What inspection procedure code is utilized when performing the HACCP basic compliance/noncompliance procedure?

3. What regulatory action is taken if noncompliance is found with the basic regulatory requirements?

4. What is the new procedure code that will be utilized by inspection personnel to determine compliance/noncompliance with the SSOP basic requirements?

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Workshop

Instructions:

This workshop contains four parts. The first part of the workshop is an example. The same HACCP documents are used for **all** parts of the workshop. The HACCP documents have been altered in some of these parts to reflect situations that may be encountered by inspection personnel with implementation of the HACCP regulation.

1. The facilitator will walk through the example in Part One of the workshop using the checklist to review the establishment's HACCP documents to determine basic regulatory compliance.

2. After reviewing the example, use the checklist (FSIS Form 5000.1) to determine basic regulatory compliance.

3. Assume that Establishment 38's records show evidence of validation prior to implementation.

4. If noncompliance is found, complete a Noncompliance Record (NR) for each part. Additional information needed to complete the NR is as follows:

   - The date is January 26, 1999.
   - Record number to use for the first NR is 2-99.
   - Establishment number is 00038—M.
   - Responsible establishment official is Ms. Linda Harris, HACCP Coordinator.
   - Personnel notified is Mr. Tom McNeil, Production Manager.
   - ISP Code is 03A01.

5. If you need assistance in completing the NR, refer to FSIS Directive 5400.5.

6. If the basic regulatory requirements are not met when performing the basic compliance/noncompliance procedure, the completed checklist will be attached to the file copy of the NR. If no noncompliance is found, the checklist will be filed in the government office.

All of the HACCP-related records and forms are designed as examples only. There is no expectation that a plant's HACCP plan or records will look like these examples.